

PATENT COOPERATION TREATY

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AUG 14 2007

From the INTERNATIONAL SEARCHING AUTHORITY

PCT BROMBERG & SUNSTEIN LLP

To:

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~~REGISTERED MAIL~~

INVITATION TO PAY ADDITIONAL FEES

(PCT Article 17(3)(a) and Rule 40.1)

Date of mailing (day/month/year)	07/08/2007
Applicant's or agent's file reference 2960/138WO	PAYMENT DUE within ONE MONTH from the above date of mailing
International application No. PCT/US2007/064349	International filing date (day/month/year) 20/03/2007
Applicant CONFORMIS, INC.	

1. This International Searching Authority

- (i) considers that there are 6 (number of) inventions claimed in the international application covered by the claims indicated ~~XXX~~ on the extra sheet:

and it considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated ~~XXX~~ on the extra sheet:

- (ii) ☒ has carried out a partial international search (see Annex) ☐ will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:

see annex

- (iii) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid

2. The applicant is hereby invited, within the time limit indicated above, to pay the amount indicated below:

EUR 1.615,00 x 5 = EUR 8.075
Fee per additional invention number of additional inventions total amount of additional fees

Or, _____ x _____ = _____

The applicant is informed that, according to Rule 40.2(c), the payment of any additional fee may be made under protest, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive.

3. ☒ Claim(s) Nos. see annex have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority



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Elisabeth Reinecke

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-12,94-104

An implant interposed in a joint between a first articular surface and a second articular surface, the implant comprising:

a first surface for contacting the first articular surface such that motion of the implant is constrained; and
a second surface for contacting the second articular surface, the second surface allowing movement of the second articular surface.

2. claims: 13-23,56-65

An implant for insertion in a joint having a first articular surface, the implant comprising:

a first implant surface conforming to the first articular surface, the first articular surface including cartilage.

3. claims: 24-55

An implant for insertion in a joint between a first articular surface and a second articular surface, the implant comprising:

a first implant surface for engaging the first articular surface, the first implant surface having one or more convexities and one or more concavities; and
a second implant surface for engaging the second articular surface, the second implant surface having at least one of a plurality of concavities and a plurality of convexities.

4. claims: 66-70

An interpositional implant suitable for a knee joint, the implant comprising:

a superior surface arranged to oppose at least a portion of a femur; and
an inferior surface arranged to oppose at least a portion of a tibial surface, wherein
the implant has a substantially U-shaped cross-section in at least one of a medial-lateral direction and an anterior-posterior direction.

5. claims: 71-76

An interpositional implant suitable for a knee joint, the implant comprising:
a superior surface arranged to contact at least a portion of a femur;
an inferior surface arranged to contact at least a portion of a tibial surface, the superior surface and the inferior surface facing opposing directions and defining a thickness;
and
a peripheral edge extending between the superior and inferior surfaces, the greatest thickness at the peripheral edge being at least 2 mm more than the smallest thickness of the implant.

6. claims: 77-93

An implant for insertion in a joint between a first articular surface and a second articular surface, the implant comprising:
a first implant surface conforming to the first articular surface, the first articular surface including cartilage, the first implant surface having a periphery, the periphery including a stabilization mechanism for limiting motion of the implant in the joint; and
a second implant surface for contacting the second articular surface.

The common concept linking group of claims 1-12, 94-104 and group of claims 13-23, 56-65 is an implant for insertion in a joint having a first articular surface, the implant comprising a first implant surface for contacting the first articular surface. This concept, however, is well known in the state of the art as exemplified by EP-A-1327423. There is no common "special technical feature" in terms of Rule 13.2 PCT linking the two groups of claims. Furthermore, the distinguishing feature of the first group of claims is that the motion at the first articular surface is constrained, whereas the distinguishing feature of the second group of claims is that the first implant surface conforms to the first articular surface. As such, the two groups of claims are directed towards solving different technical problems - the first group of claims addresses the problem of fixing the implant and the second group of claims addresses the problem of patient comfort. Therefore, there cannot be seen any corresponding "special technical feature" linking the two groups of claims, therefore the requirement for unity according to Rule 13.1 PCT is not fulfilled.

The common concept linking group of claims 1-12, 94-104 and group of claims 24-55 is an implant for insertion in a joint between a first articular surface and a second articular surface; the implant comprising a first implant surface for contacting the first articular surface and a second implant surface for contacting the second articular surface. This concept is again well known in the state of the art as exemplified by EP-A-1327423. There is no common "special technical feature" in terms of Rule 13.2 PCT linking the two groups of claims. Furthermore, the distinguishing feature of the first group of claims is that the motion at

the first articular surface is constrained, whereas the distinguishing feature of the third group of claims is that the first implant surface and the second implant surface have convexities and/or concavities. As such, the two groups of claims are directed towards solving different technical problems - the first group of claims addresses the problem of fixing the implant, as mentioned above, and the third group of claims addresses the problem of achieving a stable but mobile implant. Again, there cannot be seen any corresponding "special technical feature" linking the two groups of claims, therefore the requirement for unity according to Rule 13.1 PCT is not fulfilled.

The common concept linking group of claims 1-12, 94-104 and group of claims 66-70 is an interpositional implant comprising an inferior surface arranged to oppose at least a portion of a first articulating surface and a superior surface arranged to oppose at least a portion of a second articulating surface. This concept, however, is well known in the state of the art as exemplified by EP-A-1327423. There is no common "special technical feature" in terms of Rule 13.2 PCT linking the two groups of claims. Furthermore, the distinguishing feature of the first group of claims is that the motion at the first articular surface is constrained, whereas the distinguishing feature of the fourth group of claims is that the implant has a substantially U-shaped cross-section in at least one of a medio-lateral direction and an anterior-posterior direction. As such, the two groups of claims are directed towards solving different technical problems - the first group of claims addresses the problem of fixing the implant and the fourth group of claims addresses the problem of improving the fit of the implant within the articulation. Again, there cannot be seen any corresponding "special technical feature" linking the two groups of claims, therefore the requirement for unity according to Rule 13.1 PCT is not fulfilled.

The common concept linking group of claims 1-12, 94-104 and group of claims 71-76 is again an interpositional implant comprising an inferior surface arranged to oppose at least a portion of a first articulating surface and a superior surface arranged to oppose at least a portion of a second articulating surface. As mentioned above, this concept is well known in the state of the art as exemplified by EP-A-1327423. There is no common "special technical feature" in terms of Rule 13.2 PCT linking the two groups of claims. Furthermore, the distinguishing feature of the first group of claims is that the motion at the first articular surface is constrained, whereas the distinguishing feature of the fifth group of claims is that the implant has a peripheral edge extending between the superior and inferior surfaces, the greatest thickness at the peripheral edge being at least 2 mm more than the smallest thickness of the implant. As such, the two groups of claims are directed towards solving different technical problems - the first group of claims addresses the problem of fixing the implant and the fifth group of claims addresses the problem of achieving an implant of appropriate thickness. Again, there cannot be seen any corresponding "special technical feature" linking the two groups of claims, therefore the requirement for unity according to Rule 13.1 PCT is not fulfilled.

The common concept linking group of claims 1-12, 94-104 and group of claims 77-93 is an implant for insertion in a joint between a first articular surface and a second articular surface, the implant comprising

a first implant surface for contacting the first articular surface and a second implant surface for contacting the second articular surface. This concept, however, is well known in the state of the art as exemplified by EP-A-1327423. There is no common "special technical feature" in terms of Rule 13.2 PCT linking the two groups of claims. Furthermore, the distinguishing feature of the first group of claims is that the motion at the first articular surface is constrained, whereas the distinguishing feature of the sixth group of claims is that the first implant surface has a periphery, the periphery including a stabilization mechanism for limiting motion of the implant in the joint. As such, the two groups of claims are directed towards solving different technical problems - the first group of claims addresses the problem of fixing the implant and the sixth group of claims addresses the problem of avoiding dislocation of the implant. Again, there cannot be seen any corresponding "special technical feature" linking the two groups of claims, therefore the requirement for unity according to Rule 13.1 PCT is not fulfilled.

The application relates to a plurality of inventions, or groups of inventions, in the sense of Rule 13.1 PCT. They have been divided as defined above. If the applicant pays additional fees for one (or more) not yet searched group(s) of invention(s), then the further search(es) may reveal further prior art that gives evidence of a further lack of unity 'a posteriori' within one (or more) of the not yet searched group(s). In such a case only the first invention in this (each of these) group(s) of inventions, which is considered to lack unity of invention, will be the subject of a search. No further invitation to pay further additional fees will be issued. This is because Article 17(3)(a) PCT stipulates that the ISA shall establish the International Search Report on those parts of the international application which relate to the invention first mentioned in the claims ('main invention') and for those parts which relate to inventions in respect of which the additional fees were paid. Neither the PCT nor the PCT guidelines provide a legal basis for further invitations to pay further additional search fees (W17/00, point 11 and W1/97, points 11-16).

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 206

Continuation of Box 3.

Claim(s) not searched:
105-108

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

**Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH**

International Application No
PCT/US2007/064349

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
2. see 'Invitation to pay additional fees'
This communication is not the international search report which will be established according to Article 18 and Rule 43.
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 327 423 A1 (CT PULSE ORTHOPEDICS LTD [CH] ZIMMER GMBH [CH]) 16 July 2003 (2003-07-16) paragraph [0020] - paragraph [0021] paragraph [0032] - paragraph [0037] figures 1,2,4,6-8	1,4-9, 12, 94-104
X	US 2004/133276 A1 (LANG PHILIPP [US] ET AL) 8 July 2004 (2004-07-08) paragraph [0136] figures 8K,8L	1-4,7-9, 12, 94-104

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *&* document member of the same patent family

Patent Family Annex

Information on patent family members

International Application No

PCT/US2007/064349

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 1327423	A1	16-07-2003	AT 321510 T DE 60304233 T2	15-04-2006 18-01-2007
US 2004133276	A1	08-07-2004	NONE	